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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,318	10/07/2005	Natalia N. Bogdanova	38-21(15414)B	5329

27161 7590 10/22/2008

MONSANTO COMPANY  
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ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)  
ST. LOUIS, MO 63167

EXAMINER
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KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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10/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,318	<b>Applicant(s)</b> BOGDANOVA ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 7 and 9-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-2, 4, 7 and 9-14 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claims 15-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's cancellation of the claims.
4. The rejection of claims 14 and 19 under 35 U.S.C. 102(b) as being anticipated by Donovan et al (1994, US Patent 5,322,687) taken with the evidence of GenBank Accession No. Q45739 (2007) is withdrawn in light of Applicant's amendment or cancellation of the claims.
5. The rejection of claims 14 and 19-22 under 35 U.S.C. 103(a) as being unpatentable over Donovan et al (1994, US Patent 5,322,687) is withdrawn in light of Applicant's amendment or cancellation of the claims.
6. The rejection of claims 15-16 under 35 U.S.C. 103(a) as being unpatentable over Donovan et al (1994, US Patent 5,322,687) as applied to claims 14 and 19-22 above, and further in view of van Dun et al (WO 99/23233) is withdrawn in light of Applicant's cancellation of the claims.
7. The objection to claim 22 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of Applicant's cancellation of the claim.
8. The indicated allowability of claims 1-2, 4, 7, and 9-13 is withdrawn in view of the newly discovered reference(s) below. Rejections based on the newly cited reference(s) follow.

***Claim Rejections - 35 USC § 103***

9. Claims 1-2, 4, 7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan et al (1994, US Patent 5,322,687) in view of Koziel et al (WO 93/07278).

The claims are drawn to nucleic acid comprising bases 7-1803 of SEQ ID NO:3, bases 2650-4446 of SEQ ID NO:5, bases 3047-4844 of SEQ ID NO:8, bases 1247-3043 of SEQ ID NO:11 or bases 1658-3454 of SEQ ID NO:13, methods of making plants and plant cells comprising the nucleic acid operably linked to promoters, and plants and plant cells thereby obtained.

Donovan et al (1994, US Patent 5,322,687) Donovan et al teach a nucleic acid encoding amino acids 2-600 of SEQ ID NO:2 and amino acids 3-601 of SEQ ID NOs:4, 7, 10, 12 and 14; the protein they call cryET4 is identical to the instant cry1Bb. Donovan et al also teach a method of producing a transgenic plant resistant to lepidopteran infestation by transformation with the nucleic acid operably linked to a promoter (column 11, lines 1-12). The nucleic acid taught by Donovan et al would comprise at least a dinucleotide of SEQ ID NO:3, and thus comprises “a” nucleotide sequence as set forth in SEQ ID NO:3, 5, 8, 11 or 13. The plants are samples comprising such a nucleotide sequence.

Donovan et al also teach nucleic acid encoding a cry protein they call CryET5 and plants comprising both cryET4 and another Cry1Bb protein, cryET5 (column 5, lines 40-42).

Donovan et al do not disclose bases 7-1803 of SEQ ID NO:3, bases 2650-4446 of SEQ ID NO:5, bases 3047-4844 of SEQ ID NO:8, bases 1247-3043 of SEQ ID NO:11 or bases 1658-3454 of SEQ ID NO:13.

Kozziel et al teach codon optimization of Cry endotoxin encoding sequences, using codons most preferred in target plants (pg 4, ¶ spanning pg 5-6; pg 15, ¶2, to pg 16, ¶2, examples 2-3, 7). Maize cells that had been transformed with such a sequence had 20,000 X more Cry endotoxin than maize cells that had been transformed with the wild-type sequence (pg 133, ¶2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to codon optimize the sequence taught by Donovan et al by the method taught by Kozziel et al. One of ordinary skill in the art would have been motivated to do so because of the great increase in the level of endotoxin production (Kozziel et al, pg 133, ¶2). Bases 7-1803 of SEQ ID NO:3, bases 2650-4446 of SEQ ID NO:5, bases 3047-4844 of SEQ ID NO:8, bases 1247-3043 of SEQ ID NO:11 and bases 1658-3454 of SEQ ID NO:13 are among the possible codon-optimized sequences that encode amino acids 2-600 of SEQ ID NO:2, and amino acids 3-601 of SEQ ID NOs: 7, 10, 12 and 14. Absent a showing that these particular nuclear acids produced unexpected results over what would be expected for other plant codon-optimized sequences that encode these proteins, the claimed sequences are obvious in view of the art. It would be obvious to obtain seed from the transformed plants, as this is the form sold to farmers.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to select P-FMV or P-e35S from the commonly used promoters that function in plants, L-Os.βtub or L-Ta.Cab from the commonly used leader sequences that function in plant gene expression, I-OS.PAL or I-Os.Act1 from the commonly used plant introns, TP-Zm.rbcs from the commonly used chloroplast targeting sequences, and/or T-OS.Ldh or T-Ta.Hsp17 from the commonly used transcription terminators and polyA sequences and use them with bases 7-1803

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of SEQ ID NO:3, bases 2650-4446 of SEQ ID NO:5, bases 3047-4844 of SEQ ID NO:8, bases 1247-3043 of SEQ ID NO:11 or bases 1658-3454 of SEQ ID NO:13 to make SEQ ID NO:5, 8, 11 and 13. Absent a showing that these particular promoters, leader sequences and terminators produced unexpected results over what would be expected for other promoters, leader sequences and terminators, the claimed sequences are obvious in view of the art.

### *Conclusion*

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, Ph.D., whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 22, 2008

/Anne R. Kubelik/

Primary Examiner, Art Unit 1638